



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-2881]

Standards-Based Approach to Analytical Performance Evaluation of Next Generation

Sequencing In Vitro Diagnostic Tests; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following public workshop entitled “Standards-Based Approach to Analytical Performance Evaluation of Next Generation Sequencing In Vitro Diagnostic Tests”. The purpose of this workshop is to obtain feedback on possible analytical standards and approaches to develop or build on existing standardization efforts in order to optimize FDA’s regulatory approach to next generation sequencing (NGS)-based in vitro diagnostic tests. Comments and suggestions generated through this workshop will also guide the use of regulatory science to advance the development of appropriate and relevant performance standards for evaluation of NGS in vitro diagnostic tests that produce results on variation in the human genome.

DATES: Date and Time: The public workshop will be held on November 12, 2015, from 8 a.m. to 5 p.m.

ADDRESSES: Location: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver

Spring, MD 20993-0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to

<http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

FOR FURTHER INFORMATION CONTACT: Contact Person: Zivana Tezak, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4544, Silver Spring, MD 20993, 301-796-6206, [zivana.tezak@fda.hhs.gov](mailto:zivana.tezak@fda.hhs.gov).

Registration: Registration is free and available on a first-come, first-served basis. Persons interested in attending this public workshop must register online by 4 p.m. on October 30, 2015. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permits, onsite registration on the day of the public workshop will be provided beginning at 7 a.m.

If you need special accommodations due to a disability, please contact Susan Monahan, 301-796-5661, [susan.monahan@fda.hhs.gov](mailto:susan.monahan@fda.hhs.gov), no later than 4 p.m. on October 29, 2015.

To register for the public workshop, please visit FDA's Medical Devices News, Events, Workshops and Conferences calendar at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>. (Select this public workshop from the posted events list.) Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone number. Those without Internet access should contact Susan Monahan to register. Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

Streaming Webcast of the Public Workshop: This public workshop will also be Webcast. Persons interested in viewing the Webcast must register online by October 30, 2015, at 4 p.m. Early registration is recommended because Webcast connections are limited. Organizations are requested to register all participants, but to view using one connection per location. Webcast participants will be sent technical system requirements after registration and will be sent connection access information after November 3, 2015. If you have never attended a Connect Pro event before, test your connection at [https://collaboration.fda.gov/common/help/en/support/meeting\\_test.htm](https://collaboration.fda.gov/common/help/en/support/meeting_test.htm). To get a quick overview of the Connect Pro program, visit [http://www.adobe.com/go/connectpro\\_overview](http://www.adobe.com/go/connectpro_overview). (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.)

Requests for Oral Presentations: This public workshop includes a public comment session. During online registration you may indicate if you wish to present during a public comment session, and which topics you wish to address. FDA has included general topics in this document which will be addressed in greater detail in a subsequent discussion paper (see SUPPLEMENTARY INFORMATION). FDA will do its best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the focused sessions. All requests to make oral presentations must be received by October 26, 2015. FDA will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by October 30, 2015. If selected for presentation, any presentation materials must be emailed to Živana Tezak (see Contact Person) no later than November 5, 2015,

at 5 p.m. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

Comments: FDA is holding this public workshop to obtain feedback on possible analytical standards and approaches to develop or build on existing standardization efforts in order to optimize FDA's regulatory approach to NGS-based in vitro diagnostic tests. In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the public workshop topics. The deadline for submitting comments related to this public workshop is November 25, 2015, at 4 p.m.

Regardless of attendance at the public workshop, interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. In addition, when responding to specific topics as described in section II of this document, please identify the topic you are addressing. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (see Comments). A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. The Freedom of Information office address is available on the Agency's Web site at

<http://www.fda.gov>. A link to the transcripts will also be available approximately 45 days after the public workshop on the Internet at

<http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>. (Select this public workshop from the posted events list.)

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In vitro diagnostic devices, including laboratory-developed tests, that utilize NGS technology to generate information on an individual's genome are rapidly transforming healthcare. As part of the White House's Precision Medicine Initiative, FDA envisions implementing a novel framework for NGS test regulation that includes developing sufficiently flexible assay performance standards that can accommodate innovation, including test modifications, while assuring NGS test safety and effectiveness. To start this discussion, FDA drafted a discussion paper and held an open public workshop titled "Optimizing FDA's Regulatory Oversight of Next Generation Sequencing Diagnostic Tests" in February 2015 to discuss and receive feedback from the community on possible regulatory approaches to NGS-based diagnostic tests. Workshop material including the discussion paper can be accessed at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm427296.htm>. The workshop announced in this document seeks to build on the feedback FDA received at the public workshop in February 2015, with a goal to assess standard needs, propose performance standard content, and help in the development of the standards necessary for this effort. The Agency is therefore requesting public input on the proposed standards-based regulatory strategy for NGS tests that produce results on variation in the human genome.

## II. Topics for Discussion at the Public Workshop

This public workshop will consist of brief presentations to provide information to frame the goals of the workshop and interactive discussions via several panel sessions. Following the presentations, there will be a moderated discussion where participants and additional panelists will be asked to provide their individual perspectives. The workshop discussion will focus on standards-based regulatory strategies to assure the analytical validity of NGS tests that produce results on variation in the human genome.

The presentations and discussions will focus on several topics, including an example of a possible performance standard (methods) focusing on a single intended use; a general framework and architecture for standard needs, including currently existing guidelines and standards to be developed; and possible different approaches.

In advance of the meeting, FDA plans to post a white paper outlining FDA's most current thinking for a standards-based approach to analytical performance evaluation of NGS diagnostic tests and a summary of the issues FDA believes need consideration at the workshop at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>. (Select this public workshop from the posted events list.) FDA will place the discussion paper on file in the public docket (docket number found in brackets in the heading of this document) and will post it at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>. The deadline for submitting comments on this document for presentation at the public workshop is October 26, 2015, although comments related to this document can be submitted until November 25, 2015. A detailed agenda will be posted on this Web site in advance of the workshop.

Dated: September 2, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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